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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,628	10/22/2003	Kenneth M. Adams	2401.142-US	4034

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01/11/2007

EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/689,628

Applicant(s)

ADAMS, KENNETH M.

Examiner

Katherine M. Dowe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/18/2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 35 of U.S. Patent No 6,312,438. In the patent, claim 35 is dependent on claim 34. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1 and 9 recite "an elongate outer tubular member" (see line 2 of claim 34 of the patent) "having a bend" (see line 2 of claim 34 of the patent) and "an opening at a distal end" (see line 4 of claim 34 of the patent) defining a cutting port (see lines 8-10 of claim 34 of the patent). "An elongate flexible inner tubular member is rotatably

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disposed within the outer tubular member” (see lines 5-8 of claim 34 of the patent). The inner tubular member comprises a solid tube with “a continuous helical cut formed in a step pattern at an angle in a first direction to impart flexibility” (see lines 2-3 of claim 35 of the patent). “A cutting configuration is carried at the distal end of the inner tube and is exposed to anatomical tissue through the cutting port to cut the tissue when the inner tubular member is rotated within the outer tubular member” (see lines 8-12 of claim 34 of the patent). “A single layer of spiral wrap is disposed over the helical cut in an angle in a second direction opposite the first direction” (see lines 4-7 of claim 35 of the patent). The flexible inner tube further comprises “an aspiration passage through the inner tube” (see lines 12-15 of claim 34 of the patent) and “an aspiration port at the distal end of the inner tube establishing communication with the aspiration passage” (see lines 16-19 of claim 34 of the patent).

It is clear that all the elements of claims 1 and 9 are to be found in claim 35 (as it encompasses claim 34). The difference between claims 1 and 9 of the application and claim 35 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 35 of the patent is in effect a “species” of the “generic” invention of claims 1 and 9. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1 and 9 are anticipated by claim 35 of the patent, they are not patentably distinct from claim 35.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 2 recites the limitation "the length (of said outer tubular member)" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 3 recites the limitation "said length portions" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 only recites "a length portion...corresponding to said bend" and Claim 2 only recites "a plurality of bends".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 6, 8-16, and 20-22, are rejected under 35 U.S.C. 102(b) as being anticipated by Trott et al. (US 4,646,738). Regarding claims 1, 9, 11, and 13, Trott et al. disclose an angled tissue cutting instrument (Fig 3) comprising an elongate angled outer tubular member (12) having a bend (24) and an opening

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(18) at a distal end defining a cutting port. An elongate flexible inner tubular member (40) is rotatably disposed within the outer tubular member (12) capable of transmitting torque. The inner tubular member comprises a solid tube with a continuous helical cut formed in a step pattern at an angle in a first direction to impart flexibility by which the inner tube conforms to the outer tubular member (Fig 7, element 60). A cutting configuration (Fig 3, element 20) is carried at the distal end of the inner tube and is exposed to anatomical tissue through the cutting port to cut the tissue when the inner tubular member is rotated within the outer tubular member. A single layer of spiral wrap (Fig 7, element 64) is disposed over the helical cut in an angle in a second direction opposite the first direction. Furthermore, the inner tubular member comprises an aspiration passage (62) and an aspiration port (21) at the distal end (col 8, lines 3-19).

Regarding claim 6, Trott et al. discloses the single layer of spiral wrap (64) comprises a continuous strip of material spirally wound over the inner tube (col 7, lines 30-35).

Regarding claims 7, 8, 12, 16, and 22, Trott et al. discloses the helical cut is formed in a stepped pattern repeating interconnected steps the steps repeat at rotational intervals of 100 degrees about the inner tube (Fig 7).

Regarding claims 10 and 20, Trott et al. disclose the angle of the bend (24) is about 15-20 degrees (Fig 3).

Regarding claims 14 and 15, Trott et al. disclose a method of fabricating an angled tissue cutting instrument comprising forming a continuous helical cut with a strip of flat stainless steel ribbon along a length portion of an elongate solid

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inner tube, which may also be used for a straight cutting instrument, at an angle in a first direction to impart flexibility, wrapping a continuous strip of material spirally over the helically cut length of the inner tube in a second opposite direction, securing the opposing ends, and inserting the flexible tubular member for rotation within an angled outer tubular member (col 7, lines 21-55).

Regarding claim 21, Trott et al. discloses the step of inserting the inner tubular member into the outer tubular member comprises providing a clearance to allow for irrigating of fluid (col 8, lines 3-20).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trott et al. (US 4,646,738), as applied to claim 1 above, in view of Aznoian et al. (US 5,908,381). Trott et al. disclose the invention substantially as claimed. However, Trott et al. do not disclose the cutting instrument has a plurality of bends. Aznoian et al. disclose a similar endoscopic instrument with a plurality of bends that extend in different directions at different angles (Fig 1, elements 50 and 52), where the proximal bend (52) is bent at a first angle of 45 degrees from the proximal length portion and the distal bend (50) is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion (col 6, lines 39-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Trott et al. such that the cutting instrument comprised a second bend that extends in a different direction at a different angle, such that the proximal bend is bent at a first angle of 45 degrees from the proximal length portion and the distal bend is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion. Thus, the instrument would be easier for the surgeon to manipulate around tortuous paths. Furthermore, it would be obvious to modify the device of Trott et al. to include a plurality of helical cuts and single layers of spiral wrap along the additional length portions created with the additional bends because Trott et al. teaches the helical cuts and the spiral wrap enhance the function of the cutting instrument and impart flexibility at the bends (col 7, lines 21-54).

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11. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trott et al. (US 4,646,738), as applied to claim 14 above, in view of the applicant's disclosure. Trott et al. disclose the invention substantially as claimed. However, Trott et al. do not disclose the ideal length of the tissue cutting instrument. The applicant discloses "angled tissue cutting instruments are commonly available in the same diametric sizes as straight tissue cutting instruments, and representative standard diametric sizes for angled tissue cutting instruments include 2.9 mm, 3.5 mm, 4.0 mm, and 4.5 mm" (page 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a standard in the art using readily available sizes and modify the device of Trott et al. such that the inner tubular diameters were 2.9 mm, 3.5 mm, or 4.0 mm.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,529,580 – Kusunoki et al.

US 6,533,749 – Mitusina et al.

US 6,814,734 – Chappuis et al.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
December 22, 2006



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER